

Atty Dkt No. 3400-0008.01
PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:

Leonard W. KAPLAN et al.

Confirmation No.: Unassigned

Serial No.: 10/824,711

Group Art Unit: Unassigned

Filing Date: April 14, 2004

Examiner: Unassigned

Title: FORMULATIONS OF MOMETASONE AND A BRONCHODILATOR FOR
PULMONARY ADMINISTRATION

INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This is an Information Disclosure Statement submitted for the Examiner's consideration. Applicants respectfully request that the Examiner review and make of record the references identified below.

The majority of the references identified below were disclosed and/or cited in parent application Serial No. 09/920,340, filed August 1, 2001. As such, copies of the references are not included pursuant to the provisions of 37 CFR § 1.98(d). U.S. Patent Numbers 4,866,051 and 6,183,782 are newly cited, however, as the subject application was filed after June 30, 2003, copies of these U.S. patents are not required and, therefore, are not included.

A PTO-1449 form listing the references accompanies this paper. Applicants would appreciate the Examiner's initialing and returning the form to indicate that the references have been reviewed and made of record. The references are as follows:

U.S. PATENT DOCUMENTS		
Document No.	Issue Date or Publication Date	Name of Patentee or Applicant
4,472,393	9/18/84	Shapiro
4,866,051	9/12/89	Hunt et al.
5,126,123	6/30/92	Johnson
5,688,782	11/18/97	Neale et al.
5,837,699	11/17/98	Sequeira et al.
5,955,439	9/21/99	Green
6,030,604	2/29/00	Trofast

U.S. PATENT DOCUMENTS		
Document No.	Issue Date or Publication Date	Name of Patentee or Applicant
6,057,307	5/2/00	Sequeira et al.
6,183,782	2/6/01	Hallworth

FOREIGN PATENT DOCUMENTS		
Document No.	Publication Date	Country
EP 1201242 A2	5/2/02	Europe
EP 1236467 A1	9/4/02	Europe
WO 00/51591	9/8/00	PCT
WO 00/53187	9/14/00	PCT
WO 01/78740	10/25/01	PCT
WO 01/78744	10/25/01	PCT
WO 02/05784	1/24/02	PCT
WO 02/49616	6/27/02	PCT

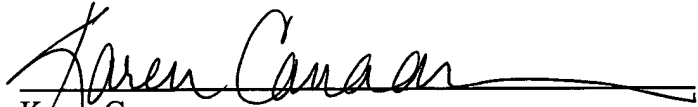
NONPATENT DOCUMENTS
"Maxair Inhaler," <i>PDR 50th Edition</i> , pp. 1494-1495 (1996).
BERNSTEIN et al. (1999), "Dose-Ranging Study of a New Steroid for Asthma: Mometasone Furoate Dry Powder Inhaler," <i>Respiratory Medicine</i> 93(9):603-612.
CHAPMAN et al. (1999), "Salmeterol and Fluticasone Propionate (50/250 µg) Administered via Combination Diskus Inhaler: As Effective as When Given via Separate Diskus Inhalers," <i>Can. Respir. J.</i> 6(1):45-51.
CHAPMAN et al. (1998), "Anti-Inflammatory Activity of Inhaled Mometasone Furoate in Allergic Mice," <i>Arzneimittelforschung</i> 48:384-391.
GLAXO GROUP (1999), Patient Information Leaflet on "Ventide."
KELSON et al. (1999), "Salmeterol Added to Inhaled Corticosteroid Therapy Is Superior to Doubling the Dose of Inhaled Corticosteroids: A Randomized Clinical Trial," <i>Journal of Asthma</i> 36(8):703-715.
LUMRY (1999), "A Review of the Preclinical and Clinical Data of Newer Intranasal Steroids Used in the Treatment of Allergic Rhinitis," <i>J. Allergy Clin. Immunol.</i> 104(4 Pt. 1):S150-S158.
NAYAK et al. (2000), "Once-Daily Mometasone Furoate Dry Powder Inhaler in the Treatment of Patients with Persistent Asthma," <i>Annals of Allergy, Asthma, & Immunology</i> 84:417-424.
Patient Information Leaflet on Ventide, Glaxo Group, 1999

This Information Disclosure Statement is not intended as a representation that a search has been made, that additional information material to the examination of this application does not exist, or that any of the above references constitutes prior art to the present application within the meaning of 35 USC § 102.

As applicants have not yet received a first Action on the merits, no fee is required for filing this Information Disclosure Statement. If, however, the PTO finds that for some reason a fee is found to be necessary, our Deposit Account No. 18-0580 may be charged therefor.

Respectfully submitted,

By:

A handwritten signature in black ink, appearing to read "Karen Canaan", written over a horizontal line.

Karen Canaan

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Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 of 1

Complete if Known

Application Number	10/824,711
Filing Date	April 14, 2004
First Named Inventor	Leonard W. KAPLAN et al.
Art Unit	Unassigned
Examiner Name	Unassigned
Attorney Docket Number	3400-0008.01

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.	Document No.	Issue Date or Publication Date	Name of Patentee or Applicant of Cited Document	Class	Subclass	Filing Date if Appropriate
	AA	4,472,393	9/18/84	Shapiro			
	AB	4,866,051	9/12/89	Hunt et al.			
	AC	5,126,123	6/30/92	Johnson			
	AD	5,688,782	11/18/97	Neale et al.			
	AE	5,837,699	11/17/98	Sequeira et al.			
	AF	5,955,439	9/21/99	Green			
	AG	6,030,604	2/29/00	Trofast			
	AH	6,057,307	5/2/00	Sequeira et al.			
	AI	6,183,782	2/6/01	Hallworth			

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.	Foreign Patent Document No.	Publication Date	Country	Class	Subclass	T
	AJ	EP 1201242 A2	5/2/02	Europe			
	AK	EP 1236467 A1	9/4/02	Europe			
	AL	WO 00/51591	9/8/00	PCT			
	AM	WO 00/53187	9/14/00	PCT			
	AN	WO 01/78740	10/25/01	PCT			
	AO	WO 01/78744	10/25/01	PCT			
	AP	WO 02/05784	1/24/02	PCT			
	AQ	WO 02/49616	6/27/02	PCT			

OTHER DOCUMENTS — NONPATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), Title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T
	AR	"Maxair Inhaler," <i>PDR 50th Edition</i> , pp. 1494-1495 (1996).	
	AQ	BERNSTEIN et al. (1999), "Dose-Ranging Study of a New Steroid for Asthma: Mometasone Furoate Dry Powder Inhaler," <i>Respiratory Medicine</i> 93(9):603-612.	
	AS	CHAPMAN et al. (1999), "Salmeterol and Fluticasone Propionate (50/250 µg) Administered via Combination Diskus Inhaler: As Effective as When Given via Separate Diskus Inhalers," <i>Can. Respir. J.</i> 6(1):45-51.	
	AT	CHAPMAN et al. (1998), "Anti-Inflammatory Activity of Inhaled Mometasone Furoate in Allergic Mice," <i>Arzneimittelforschung</i> 48:384-391.	
	AU	GLAXO GROUP (1999), Patient Information Leaflet on "Ventide."	
	AV	KELSON et al. (1999), "Salmeterol Added to Inhaled Corticosteroid Therapy Is Superior to Doubling the Dose of Inhaled Corticosteroids: A Randomized Clinical Trial," <i>Journal of Asthma</i> 36(8):703-715.	
	AW	LUMRY (1999), "A Review of the Preclinical and Clinical Data of Newer Intranasal Steroids Used in the Treatment of Allergic Rhinitis," <i>J. Allergy Clin. Immunol.</i> 104(4 Pt. 1):S150-S158.	
	AX	NAYAK et al. (2000), "Once-Daily Mometasone Furoate Dry Powder Inhaler in the Treatment of Patients with Persistent Asthma," <i>Annals of Allergy, Asthma, & Immunology</i> 84:417-424.	
	AY	Patient Information Leaflet on Ventide, Glaxo Group, 1999	

Examiner
SignatureDate
Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.